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Syfait II: The European Court of Justice decision - Dominant pharmaceutical companies must meet the *ordinary* orders from wholesalers

On 16 September 2008, the European Court of Justice (the "**ECJ**") issued its much-anticipated ruling in the Syfait II case.[1] The ECJ ruling is important in that it sheds light on the extent to which dominant pharmaceutical companies may restrict supplies to wholesalers (e.g., quota schemes) in order to prevent parallel exports, without infringing EU competition law.

The ECJ held that a pharmaceutical company which occupies a dominant position on the relevant market for medicinal products and refuses to meet ordinary orders of wholesalers, in order to prevent parallel trade, abuses its dominant position under Article 82 EC.[2] The key to whether an abuse has occurred is the word "ordinary": the dominant pharmaceutical company may lawfully refuse to meet orders from wholesalers, if they are not ordinary in the light of both (i) the size of those orders in relation to the requirements of the market in the Member State of purchase and (ii) the previous business relations between the pharmaceutical company and the wholesalers concerned.

The ECJ addresses for the first time, as a matter of EU law, the questions whether, and when, a unilateral restriction of parallel trade by a dominant pharmaceutical company may infringe EU competition law. Its ruling follows two Advocate General Opinionson

1 Cases C-468/06 and C-478/06, Sot. Lelos Sia EE and others v GlaxoSmithKline AEVE, available at http://www.curia.eu.int.

2 Article 82 EC prohibits certain abusive conduct by a firm holding a dominant position on the relevant market, where that conduct cannot be objectively justified.

the same issue,[3] as well as the Bayer judgment,[4] which considered the same question despite the absence of a dominant position.

BACKGROUND

The price of medicines is regulated in Greece and prices there are lower than in many other Member States. GlaxoSmithKline AEVE ("**GSK**") is the Greek subsidiary of GlaxoSmithKline plc, which has for many years supplied Greek wholesalers with patented pharmaceutical products. The wholesalers then supply these products to Greek hospitals and pharmacies as well as exporting them to other EU Member States where the price per product is higher than in Greece. In November 2000, in order to prevent parallel trade in its products, GSK stopped supplying the wholesalers and began to supply hospitals and pharmacies through a single company, Farmacenter AE. In February 2001, it recommenced its supply to the wholesalers, but imposed a cap on the total volume of quantities it would supply in Greece – national consumption plus 18%.

One wholesaler, Syfait, complained to the Greek competition commission (the "**EA**") about GSK's conduct, and the EA referred various questions to the ECJ about the application of Article 82 EC in these circumstances. Advocate General Jacobs gave his opinion on the questions (broadly, that due to the particular nature of the pharmaceutical sector, GSK's behaviour was objectively justifiable, as a reasonable and proportionate measure in defence of its commercial interests) but the ECJ subsequently ruled that it did not have jurisdiction to rule on the questions. The EA then proceeded to hear the case, finding that GSK:

- held a dominant position in relation to only one of the three drugs in question;
- had breached Greek competition law for a period of only four months; and
- had not breached Article 82 EC.

This decision was appealed, and the Athens court of appeal referred a number of questions to the ECJ. In the Opinion that preceded the ECJ ruling, Advocate General Ruiz-Jarabo found that GSK's behaviour could not be considered as a per se abuse of a dominant position, and outlined three objective justifications for such behaviour– the specific functioning of the market, the supplier has as its sole intention the legitimate defence of its commercial interests, and economic efficiencies – which may apply. However, his view was that none of these justifications applied in GSK's case.

THE ISSUES BEFORE THE ECJ

In the Bayer case, the ECJ established that a non-dominant company, acting unilaterally, may lawfully refuse or limit supplies to wholesalers with the aim of restricting parallel trade. The question referred by the Athens court of appeal to the ECJ is whether a dominant company may do the same.

THE ECJ RULING

First, the ECJ recalled the case law on refusal to supply and parallel trade, in respect

3 Opinion of Advocate General Jacobs and Opinion of Advocate General Ruiz-Jarabo, available at http://www.curia.eu.int.

4 Joined Cases C-2/01 P and C-3/01 P, Bundesverband der Arzneimittel-Importeure v Bayer and Commission, available at http://www.curia.eu.int.

of sectors other than pharmaceuticals. According to this case law, a practice by which a firm in a dominant position aims to restrict parallel trade in the products that it puts on the market constitutes an abuse of that dominant position.[5] Next, the ECJ went on to consider whether this case law also applies to the pharmaceutical sector in view of its specific characteristics.

THE SPECIFIC CHARACTERISTICS OF THE EU PHARMACEUTICAL SECTOR

The ECJ recognised that the pharmaceutical sector in the EU is characterised by a high degree of price and supply regulation, which sets it aside from all other sectors. The prices of medicines are largely set by each Member State. In certain countries, this price is set higher than in others, in order to reward and stimulate research and development by pharmaceutical companies. The price differences between Member States create the possibility for wholesalers to arbitrage, i.e., to purchase medicines in low-price countries and sell them in high-price countries. Parallel trade results in significant profit losses for pharmaceutical companies, whose prices are fixed by the State.

On the one hand, the ECJ found that such regulation does not necessarily justify a refusal to supply by a dominant pharmaceutical company in order to prevent parallel trade:

- parallel exports are beneficial to consumers, in that they exert pressure on the prices of medicines in the import country; and
- the impact of State price and supply regulation in the pharmaceutical sector does not entirely remove the prices of medicines from the law of supply and demand. According to the ECJ, in some Member States, pharmaceutical companies are free to decide their selling prices. In others, pharmaceutical companies have influence on the level at which the selling prices are set or the proportion of those prices that are reimbursed.

On the other hand, the ECJ recognised that State regulation is one of the factors liable to create opportunities for parallel trade, and, in such circumstances, even a dominant company must be able to defend its own commercial interests against parallel trade.

THE KEY CRITERION IS PROPORTIONALITY

According to the ECJ, the key criterion to determine whether a refusal to supply by a pharmaceutical company is abusive or not is proportionality.

In particular, a pharmaceutical company in a dominant position cannot cease to honour orders of an existing customer that are in line with that customer's previous orders. However, it must be able to take steps that are reasonable and in proportion to the need to protect its own commercial interests.[6] On this basis, a dominant company may lawfully counter the threat to its own commercial interests potentially posed by parallel exports, where the orders of a wholesaler is for an extra-ordinary quantity (this being

5 Case 26/75 General Motors Continental v Commission [1975] ECR 1367; and Case 226/84 British Leyland v Commission [1986] ECR 3263. Indeed, parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition (Case C–373/90 X [1992] ECR I–131, paragraph 12).

6 Case 27/76 United Brands and United Brands Continentaal v Commission [1978] ECR 207.

measured by having regard to the quantities previously sold by the same wholesalers to meet the needs of the market in that Member State).

In the present case, it will be for the referring Greek court to ascertain whether the orders at stake were ordinary in the light of both:

- the previous business relations between GSK and the wholesalers concerned; and
- the size of the orders in relation to the requirements of the market in Greece.

CONCLUSION

The ECJ ruling confirms that pharmaceutical companies have a legitimate commercial interest in preventing parallel trade, and that they must be able to protect such an interest even when they are in a dominant position. The key to assess whether or not a refusal to supply all or part of an order is lawful under EU competition law will be whether the order of the parallel exporter is ordinary. If it is ordinary, the refusal will not be reasonable and proportionate and the pharmaceutical company will be abusing its dominant position. The meaning of "ordinary" in any given circumstance will no doubt give rise to significant debate.

The ECJ ruling is only one piece of the jigsaw. It does not deal with the issues of market definition and dominance in the pharmaceutical sector. The first opportunity for the European Courts to decide on these issues will be the AstraZeneca case which is currently on appeal to the Court of First Instance.[7]

The Antitrust & Competition Group has a wealth of experience representing clients in all types of competition law proceedings. If you have any questions about the above news item, or would like to discuss any aspect of your own business conduct in confidence, please contact Frances Murphy or Gillian Sproul:

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7 Case T-321/05 (pending).